



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
HEADQUARTERS, US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
810 SCHREIDER STREET
FORT DETRICK, MARYLAND 21702-5000

Office of the Chief of Staff

Andrew S. Goldman
Knowledge Ecology International
1621 Connecticut Avenue, NW
Washington, D.C. 20009

Dear Mr. Goldman:

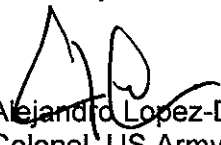
I have been asked to respond on behalf of the Secretary of Defense Ashton Carter to your January 14, 2016 letter concerning your request for the United States Federal Government to exercise its march-in rights pursuant to 35 U.S.C. § 203 to patented inventions made by the University of California with funding from the National Institutes of Health (NIH) and the Department of Defense (DoD).

A federal agency that funded an invention has the right, consistent with 35 U.S.C. § 203(a)(1), to grant a license to a third party if "action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use." Practical application as defined at 35 U.S.C. § 201 is "...to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms."

Your letter and supporting material show that Xtandi® has achieved practical application as the DHHS and DoD understand that term. Your request does not disclose information suggesting that supplies of Xtandi® are running low or that health or safety needs are not being met by the manufacturer. In view of the above information, we decline to exercise the government's march-in authorities or utilize the government's license to the enzalutamide patents.

The point of contact for this letter is Major Sara Harmon, (301) 619-7111, or email sara.j.harmon2.mil@mail.mil.

Sincerely,


Alejandro Lopez-Duke
Colonel, US Army
Chief of Staff

cc: The Honorable Secretary Burwell; Secretary of Health and Human Services
Dr. Francis S. Collins, M.D., Ph.D.; Director, National Institutes of Health
The Union for Affordable Cancer Treatment (UACT)